

## WHAT IS CLAIMED IS:

1. A method for determining an analyte in a sample suspected of containing said analyte comprising the steps of:
  - 5 a. combining said sample with a single stranded DNA template capable of replication and comprising a starting nucleotide sequence, a deoxyribonucleotide precursor, a DNA polymerase enzyme, a receptor capable of binding with said analyte, a compound capable of generating a detectable signal in the presence of double stranded DNA, and a primer, said primer linked to a ligand or analog of said analyte and comprising a sequence complementary to said starting sequence of said template, under conditions favorable for DNA replication,
  - 10 b. monitoring the generation of double stranded DNA by said enzyme by measuring the signal produced by said compound, and
  - 15 c. correlating the production of said signal with the presence or amount of said analyte in said sample.
2. The method of claim 1, wherein said analyte is selected from the group consisting of drugs, drug derivatives, hormones, proteins, polypeptides and oligonucleotides.
3. The method of claim 1, wherein said analyte is LSD.
- 20 4. The method of claim 1, wherein said primer is amino dT C<sub>6</sub> modified universal primer.
5. The method of claim 1, wherein said template is M13.

6. The method of claim 1, wherein said receptor is selected from the group consisting of antibodies, antibody fragments and antibody derivatives.
7. The method of claim 1, wherein said compound capable of generating a detectable signal is a DNA intercalator selected from the group consisting of PicoGreen, acridine orange, ethidium monoazide, ethidium bromide, propidium iodide, 7-aminoactinomycin D, LDS-751, ACMA, DAPI, dihydroethidium, ethidium homodimers, FluoroNissl Green, hexidium iodide, bisbenzimidazole, hydroxystilbamidine and YOYO-1.
8. The method of claim 1, wherein said intercalator is PicoGreen.
9. A reagent for determining an analyte in a sample via a method involving inhibition of DNA replication, said reagent comprising a primer bound to a ligand of said analyte or an analog of said analyte.
10. A method for determining an analyte in a sample suspected of containing said analyte comprising the steps of:
  - a. combining said sample with a single stranded DNA template capable of replication and comprising a starting nucleotide sequence, a deoxyribonucleotide precursor, a DNA polymerase enzyme, said enzyme linked to a ligand or analog of said analyte, a receptor capable of binding with said analyte, a compound capable of generating a detectable signal in the presence of double stranded DNA, and a primer, said primer comprising a sequence complementary to said starting sequence of said template, under conditions favorable for DNA replication,
  - b. monitoring the generation of double stranded DNA by said enzyme by measuring the signal produced by said compound, and

- c. correlating the production of said signal with the presence or amount of said analyte in said sample.

11. The method of claim 10, wherein said analyte is selected from the group consisting of drugs, drug derivatives, hormones, proteins, polypeptides and oligonucleotides.

5 12. The method of claim 10, wherein said primer is amino dT C<sub>6</sub> modified universal primer.

13. The method of claim 10, wherein said template is M13.

14. The method of claim 10, wherein said receptor is selected from the group consisting of antibodies, antibody fragments and antibody derivatives.

10 15. The method of claim 10, wherein said compound capable of generating a detectable signal is a DNA intercalator selected from the group consisting of PicoGreen, acridine orange, ethidium monoazide, ethidium bromide, propidium iodide, 7-aminoactinomycin D, LDS-751, ACMA, DAPI, dihydroethidium, ethidium homodimers, FluoroNissl Green, hexidium iodide, bisbenzimidazole, hydroxystilbamidine and YOYO-1.

16. The method of claim 10, wherein said intercalator is PicoGreen.

17. A reagent for determining an analyte in a sample via a method involving inhibition of DNA replication, said reagent comprising a DNA polymerase enzyme linked to a ligand or analog of said analyte.

20 18. A method for determining an analyte in a sample suspected of containing said analyte comprising the steps of:

- a. combining said sample with a single stranded DNA template capable of replication and comprising a starting nucleotide sequence, a deoxyribonucleotide precursor, a DNA polymerase enzyme, a compound

capable of generating a detectable signal in the presence of double stranded DNA, and a primer, said primer linked to a receptor capable of binding with said analyte and comprising a sequence complementary to said starting sequence of said template, under conditions favorable for DNA replication,

- 5        b.        monitoring the generation of double stranded DNA by said enzyme by measuring the signal produced by said compound, and
- c.        correlating the production of said signal with the presence or amount of said analyte in said sample.
19.     The method of claim 18, wherein said analyte is selected from the group consisting of drugs, drug derivatives, hormones, proteins, polypeptides and oligonucleotides.
20.     The method of claim 18, wherein said analyte is carcinoembryonic antigen.
21.     The method of claim 18, wherein said primer is amino dT C<sub>6</sub> modified universal primer.
22.     The method of claim 18, wherein said template is M13.
- 15 23.     The method of claim 18, wherein said receptor is selected from the group consisting of antibodies, antibody fragments and antibody derivatives.
24.     The method of claim 18, wherein said compound capable of generating a detectable signal is a DNA intercalator selected from the group consisting of PicoGreen, acridine orange, ethidium monoazide, ethidium bromide, propidium iodide, 7-aminoactinomycin D, LDS-751, ACMA, DAPI, dihydroethidium, ethidium homodimers, FluoroNissl Green, hexidium iodide, bisbenzimidazole, hydroxystilbamidine and YOYO-1.
- 20 25.     The method of claim 18, wherein said intercalator is PicoGreen.

26. A reagent for determining an analyte in a sample via a method involving inhibition of DNA replication, said reagent comprising a primer bound to a receptor capable of binding with said analyte
27. A test kit for the determination of an analyte comprising in packaged combination:
  - 5 a single stranded DNA template capable of replication and comprising a starting nucleotide sequence,
  - a primer linked to a ligand or analog of said analyte, said primer comprising a sequence complementary to said starting sequence of said template,
  - a DNA polymerase enzyme,
  - 10 a deoxyribonucleotide precursor,
  - a receptor capable of binding with said analyte, and
  - a compound capable of generating a detectable signal in the presence of double stranded DNA.
28. The kit of claim 27, wherein said analyte is selected from the group consisting of  
15 drugs, drug derivatives, hormones, proteins, polypeptides and oligonucleotides.
29. The kit of claim 27, wherein said analyte is LSD.
30. The kit of claim 27, wherein said primer is amino dT C<sub>6</sub> modified universal primer.
31. The kit of claim 27, wherein said template is M13.
- 20 32. The kit of claim 27, wherein said receptor is selected from the group consisting of antibodies, antibody fragments and antibody derivatives.

- 5 33. The kit of claim 27, wherein said compound capable of generating a detectable signal is a DNA intercalator selected from the group consisting of PicoGreen, acridine orange, ethidium monoazide, ethidium bromide, propidium iodide, 7-aminoactinomycin D, LDS-751, ACMA, DAPI, dihydroethidium, ethidium homodimers, FluoroNissl Green, hexidium iodide, bisbenzimidazole, hydroxystilbamidine and YOYO-1.
34. The kit of claim 27, wherein said intercalator is PicoGreen.
35. A test kit for the determination of an analyte comprising in packaged combination:  
10 a single stranded DNA template capable of replication and comprising a starting nucleotide sequence,  
a primer linked to a receptor capable of binding with said analyte, said primer comprising a sequence complementary to said starting sequence of said template,  
a DNA polymerase enzyme,  
a deoxyribonucleotide precursor, and  
15 a compound capable of generating a detectable signal in the presence of double stranded DNA.
36. The kit of claim 35, wherein said analyte is selected from the group consisting of drugs, drug derivatives, hormones, proteins, polypeptides and oligonucleotides.
37. The kit of claim 35, wherein said analyte is carcinoembryonic antigen.
- 20 38. The kit of claim 35, wherein said primer is amino dT C<sub>6</sub> modified universal primer.
39. The kit of claim 35, wherein said template is M13.

40. The kit of claim 35, wherein said receptor is selected from the group consisting of antibodies, antibody fragments and antibody derivatives.
41. The kit of claim 35, wherein said compound capable of generating a detectable signal is a DNA intercalator selected from the group consisting of PicoGreen, acridine orange, ethidium monoazide, ethidium bromide, propidium iodide, 7-aminoactinomycin D, LDS-751, ACMA, DAPI, dihydroethidium, ethidium homodimers, FluoroNissl Green, hexidium iodide, bisbenzimidazole, hydroxystilbamidine and YOYO-1.
42. The kit of claim 35, wherein said intercalator is PicoGreen.
43. A test kit for the determination of an analyte comprising in packaged combination:
- a single stranded DNA template capable of replication and comprising a starting nucleotide sequence,
  - a primer comprising a sequence complementary to said starting sequence of said template,
  - a DNA polymerase enzyme, said enzyme linked to a ligand or analog of said analyte,
  - a deoxyribonucleotide precursor, and
  - a compound capable of generating a detectable signal in the presence of double stranded DNA.
44. The kit of claim 43, wherein said analyte is selected from the group consisting of drugs, drug derivatives, hormones, proteins, polypeptides and oligonucleotides.
45. The kit of claim 43, wherein said primer is amino dT C<sub>6</sub> modified universal primer.

46. The kit of claim 43, wherein said template is M13.
47. The kit of claim 43, wherein said receptor is selected from the group consisting of antibodies, antibody fragments and antibody derivatives.
48. The kit of claim 43, wherein said compound capable of generating a detectable signal is a DNA intercalator selected from the group consisting of PicoGreen, acridine orange, ethidium monoazide, ethidium bromide, propidium iodide, 7-aminoactinomycin D, LDS-751, ACMA, DAPI, dihydroethidium, ethidium homodimers, FluoroNissl Green, hexidium iodide, bisbenzimidazole, hydroxystilbamidine and YOYO-1.
49. The kit of claim 43, wherein said intercalator is PicoGreen.